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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,702

04/23/2007

Jeffrey Schlom

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EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,702	<b>Applicant(s)</b> SCHLOM ET AL.	
	<b>Examiner</b> Anne M. Gussow	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-78 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 31-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 14-16 and 27-29 have been amended.  
Claim 30 has been cancelled.
2. Claims 1-13 and 31-78 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 3, 2009.
3. Claims 14-29 are under examination.

### ***Objections Withdrawn***

4. The objections to the specification are withdrawn in view of applicant's amendment to the specification.
5. The objection to claim 15 is withdrawn in view of applicant's amendment to the claim.

### ***Rejections Withdrawn***

6. The rejection of claims 27-30 under 35 U.S.C. 101 as being drawn to non-statutory subject matter is withdrawn in view of applicant's amendment to the claims.

7. The rejection of claims 14 and 16 under 35 U.S.C. 102(b) as being anticipated by Gendler, et al. (Journal of Biological Chemistry, 1990.) is withdrawn in view of applicant's amendment to the claims.

8. The rejection of claims 14, 16, 17, and 20-30 under 35 U.S.C. 102(b) as being anticipated by Thomson and Ramshaw (WO 01/90197) is withdrawn in view of applicant's amendment to the claims.

***Rejections Maintained***

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The rejection of claims 14-29 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's response filed July 9, 2009 has been carefully considered by the examiner but is deemed not to be persuasive. The response states that applicant notes that the peptides in SEQ ID NO: 2, 14, 16, and 19 have at least 90% identity to SEQ ID NO: 1 and peptides in SEQ ID NO: 15, 17, and 18 have at least 80% identity to SEQ ID NO: 1. Applicant submits that provided with the teachings of the specification, one of

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skill in the art could readily design polypeptides having at least 60% identity to the amino acid sequence of SEQ ID NO: 1-2 or 14-19 (see response pages 17-18).

In response to this argument, applicant's peptides in Table 4 provide specific substitutions at specific residues in the peptides. Applicant has not described a single mutation at each position in the peptides as encompassed by the instant claims. While the sequences of SEQ ID Nos. 2 and 14-19 have at least 80% identity to SEQ ID No. 1, they contain mutations at specific residues – positions 2 or 10. None of the residues at the other 8 positions have been substituted, even with conservative amino acid changes. Applicant argues on page 17 that the claims do not include any functional limitations, therefore no correlation between structure and function is required. The examiner respectfully disagrees with this position since claim 17 requires the peptide to bind to HLA molecules with high avidity; thus a specific function of the peptide which would be associated with the specific structure of the peptide molecule. Further, applicant has argued that the references cited in the rejection were misplaced because they relate to full length proteins, not peptides; specifically Skolnick, Burgess, and Lazar, all of record (see response page 20). Each of these references teaches that mutation of a single amino acid residue affects the function of the protein. Thus, one of ordinary skill in the art would similarly expect that mutation of a single amino acid residue in a peptide would also affect the function of a peptide. While applicant does not need to describe each and every species a representative number of species is required. Applicant has not described a representative number of peptide substitutions which would retain the function of binding to HLA molecules with high avidity.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The rejection of claim 15 under 35 U.S.C. 102(b) as being anticipated by Gendler, et al. (Journal of Biological Chemistry, 1990. Vol. 265, pages 15286-15293) is maintained.

Applicant's response filed July 9, 2009 has been carefully considered by the examiner but is deemed not to be persuasive. The response states that applicant has amended the claims to recite polypeptide sequences up to 12 amino acids in length (see response pages 21-22)

In response to this argument, claim 15 as amended recites an isolated polypeptide comprising an amino acid sequence at least 60% identical to the sequence set forth in SEQ ID No. 1. Since the claim does not limit the length of the polypeptide and uses the open "comprising" language, Gendler, et al. still reads on the claim. Gendler, et al. teach an amino acid sequence of mucin 1 which comprises the sequence of SEQ ID No. 1 as set forth in the previous office action.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

13. The rejection of claim 15 under 35 U.S.C. 102(b) as being anticipated by Thomson and Ramshaw (WO 01/90197) is maintained.

Applicant's response filed July 9, 2009 has been carefully considered by the examiner but is deemed not to be persuasive. The response states that applicant has amended the claims to recite polypeptide sequences up to 12 amino acids in length (see response pages 21-22).

In response to this argument, claim 15 as amended recites an isolated polypeptide comprising an amino acid sequence at least 60% identical to the sequence set forth in SEQ ID No. 1. Since the claim does not limit the length of the polypeptide and uses the open "comprising" language Thomson and Ramshaw, et al. still reads on the claim. Thomson and Ramshaw, et al. teach a polypeptide derived from MUC1 that comprises the sequence of SEQ ID No. 1 recognized by HLA for the induction of an immune response to activate both T cells and B cells as set forth in the previous office action.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

### ***Conclusion***

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.



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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
November 16, 2009

/Anne M. Gussow/  
Examiner, Art Unit 1643

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643